

Appl. No. 10/750,755
Amendment dated: February 11, 2005
Reply to OA of: December 1, 2004

REMARKS

Applicants have amended independent claims 1, 9 and 15 to replace the transitional phrase "comprising" with the transitional phrase "consisting essentially of." Applicants have also amended dependent claims 3, 11 and 17 to put the claims in independent form and to replace the transitional phrase "comprising" with the transitional phrase "consisting essentially of." Applicants most respectfully submit that all the claims now present in the application are in full compliance with 35 U.S.C. §112 and are clearly patentable over the references of record.

The rejection of claims 1-22 under 35 U.S.C. §103(a) as being obvious in view of Kimura et al. (US 4,810,465) has been carefully considered but is most respectfully traversed.

In the Official Office Action it is urged that Kimura discloses the invention substantially as claimed. Applicants specifically traverse this rejection in view of the following comments.

Applicants are well acquainted with the Kimura reference as it was cited, discussed and differentiated from the present invention by Applicants in the Background of the Invention at page 3 of the Specification. Kimura discloses a free-cutting titanium alloy with improved machinability for use in connecting rods in automobiles, industrial machines and the like. The present invention relates to a medical device made of a biocompatible titanium alloy having improved castability and a method to improve the castability of a titanium alloy. Thus, as a threshold matter, Kimura does not disclose the invention substantially as claimed because Kimura is directed to titanium alloy for use in connecting rods in automobiles and the like while the present invention is directed to medical devices and a method for improving castability of a titanium alloy.

Applicants present invention is drawn to improving castability, while the Kimura reference is drawn to improving machinability. Machinability is explained by Woldman and Gibbons in Machinability and Machining of Metals as follows: "The most machinable metal is the one which will permit the fastest removal of the greatest amount of material

per grind (without resharpener the tool) with a satisfactory finish.” Applicants have submitted herewith several other textbook definitions of machinability and workability for the Examiners reference. Castability is the ability of casting, where casting is defined as 1) an object at or near finished shape obtained by solidification of a substance in a mold or 2) pouring molten metal into a mold to produce an object of desired shape.

The Kimura reference focuses on improving the machinability of Ti alloy by adding S, Se, Te, Ti-S, Ca-S or REM-S. Improved machinability is beneficial since a major portion of total manufacturing cost of Ti alloy devices is spent on machining.

In contrast, the present invention focuses on improving castability by way of introducing Bi into the Ti alloy. Improved castability is also beneficial since a cost-effective way to manufacture Ti alloys is by near-shape casting which requires little or no machining. Ti alloys are inherently difficult to cast due to their high melting temperatures and high chemical reactivity. The present invention provides a simple and effective method to improve castability. The two inventions have different goals, and are thus further differentiated from each other.

Because titanium is inherently difficult to cast due to its high melting point and high reactivity, the present invention is directed to a medical device having improved castability consisting essentially of a titanium alloy and a method to improve a titanium alloy wherein the castability is greatly improved. Applicants have discovered that the introduction of Bismuth in certain amounts to various titanium alloys achieves the goal of improved castability. Such improvement can clearly be seen by referring to the comparative examples summarized in Table 1 of the application. When bismuth was melted into the various titanium samples, the castability was improved over the same titanium sample without the bismuth. Applicants further discovered that the addition of more bismuth to the titanium alloys caused the improved castability to decrease, although the castability was still improved with reference to the titanium alloy containing no bismuth.

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Kimura, on the other hand, recognizes that the machinability of both Ti and Ti alloys is inferior to that of conventional materials such as steel. As a solution, Kimura teaches that the addition of certain elements, specifically S, Se, Te, Ti-S, Ca-S and REM-S, to Ti improves the machinability of Ti alloys. The Kimura reference fails to recognize the improvement of castability caused by the addition of Bismuth to a titanium alloy and therefore does not disclose the invention substantially as claimed.

Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP. Section 2143 states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

In the Official Action it is further urged that Kimura discloses a titanium alloy comprising alloying elements selected from a group comprising Bi in an amount of 0.001-1% and alloying elements selected from a group comprising Zr up to 10% and Mo up to 15% and other additional alloying elements as claimed by Applicants and substantially overlapping those as claimed by Applicants. Applicants specifically traverse this rejection in view of the following comments.

The present invention claims a medical device made of a biocompatible titanium alloy composition having an improved castability consisting essentially of about 0.01-5 wt% Bi based on the weight of the alloy composition; at least one alloy element selected from a group consisting of Mo, Nb, Ta, Zr and Hf; and the balance Ti. Kimura, on the other hand, discloses a titanium alloy consisting of at least one from the group consisting of S, Se and Te; REM, at least one from the group consisting of Ca and B; at least one from the group consisting of Ti-S, Ca-S and REM-S and the balance being substantially Ti. Kimura also discloses in an alternate embodiment the addition of Pb or Bi to the above composition.

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The transitional phrase "consisting of" excludes any element, step or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948). Thus, the Kimura reference, which uses the transitional phrase "consisting of" in both the claims and the specification, is limited to teaching only that which is specifically identified in the embodiments set forth in the disclosure and claims. Accordingly, in order to support a §103(a) rejection, Kimura must be modified by a motivational statement or suggestion that explains why it would be obvious to one having ordinary skill in the art to add and/or remove elements specifically required by the closed language of the claims and specification. The Office Action has not provided a motivation or suggestion as to why it would have been obvious to one of ordinary skill in the art to add at least one alloy element selected from the group consisting of Mo, Nb, Ta, Zr and Hf, as required by present Claim 1, 9 and 15, to the embodiment of the Kimura reference that includes Bi.

Further, as mentioned above, a §103(a) rejection is only proper when the reference teaches or suggests all of the claim limitations. The Kimura reference fails to disclose a medical device consisting essentially of the titanium alloy as claimed by Claim 1 wherein the alloy further consists essentially of at least one eutectoid beta stabilizing element selected from the group consisting of Fe, Cr, Mn, Co, Ni, Cu, Ag, Au, Pd, Si and Sn; a medical device as set forth in Claim 1 wherein the titanium alloy composition is free from V; the medical device as set forth in Claim 1 wherein the titanium alloy composition is free from Al; the medical device as set forth in Claim 2 wherein the titanium alloy composition consists essentially of Ti and Mo; Ti and Nb; Ti and Zr; Ti, Mo and Fe; Ti, Mo and Cr; Ti, Mo and Nb; Ti, Mo and Ta; Ti, Nb and Fe; Ti, Ta and Fe; Ti, Nb and Zr; Ti, Al and Nb; Ti, Mo, Zr and Fe; or Ti, Mo, Hf and Fe, in addition to Bi; the medical device as set forth in claim 1 which is a dental casting and the medical device as set forth in claim 1 which is a medical implant. The Office Action also fails to provide any suggestion or motivation to modify the Kimura reference to meet these limitations. The same arguments are also relevant with respect to the

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method for improving castability of a titanium alloy found in Claim 9 and method of using a titanium alloy composition in making a medical device found in Claim 15.

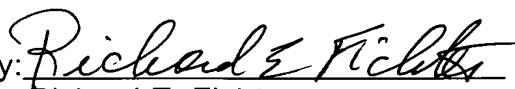
Section 2143.03 of the MPEP states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). For all of the forgoing reasons, Applicants respectfully request that the §103(a) rejection over Kimura be withdrawn and Claims 1-22 be allowed.

The rejection of claims 1-22 under the judicially created doctrine of double patenting over claims 1-3 of U.S. Patent 6,572,815 in view of Kimura et al. has been carefully considered. However, Applicant timely submits herewith a Terminal Disclaimer in compliance with 37 CFR 1.321(c) and payment of the required fee thereby obviating any obviousness type double patenting rejection.

In view of the above comments and amendments to the claims an early and favorable action on the application is now in order and is most respectfully requested.

Respectfully submitted,

BACON & THOMAS, PLLC

By: 
Richard E. Fichter
Registration No. 26,382

625 Slaters Lane, 4th Fl.
Alexandria, Virginia 22314
Phone: (703) 683-0500
Facsimile: (703) 683-1080

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